

Remarks

Claims 1-84 are pending. Claims 1 and 65-82 were previously elected for examination. As requested by the Examiner, Applicants have amended the beginning of the specification to provide status information regarding all related applications.

Applicants thank the Examiner for taking the time to discuss the responses to related Application Nos. 10/856,925; 10/856,926; 11/190,724 and the instant Application as a group during the interview of July 10, 2007.

Applicants have amended claims 80-82 to recite individual hollow and individual porous filaments to clarify these elements in the claims. Support for these amendments is found in the specification as a whole and, for example, paragraph [0080] of the specification as filed on March 24, 2004. Applicants have also amended claim 78 to recite non-conductive filaments having a greater length than the conductive filaments. Support for this amendment is also found in the specification as a whole and, for example, paragraph [0056] and Figs. 8-10 of the specification as filed.

No new matter is added by these amendments.

Claim 77 stands rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has requested that Applicants show the support in the original disclosure for an annular layer of porous material. Applicants respectfully point out that paragraph [0069] of the specification as filed describes the annular layer of porous material as well as some of its functions.

Arguments addressed to claims 65-68, 72, 75-77 and 79-82

Rejections under 35 U.S.C. § 102(b)

Claims 65-68, 72, 75-77 and 79-82 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Goble.

Claim 65 is independent. All rejected dependent claims depend from claim 65.

The totality of Examiner's rejection under 102(b) is as follows:

The patent discloses:

A catheter comprising an outer sheath (12), inner sheath (16), annular channel (17), a porous (figure 13 – fluid 17 emitted through 15 out of distal element 13) mechanical interface (15), clustered (54, figure 7b) hollow and wire electrodes (11; col. 25:36-37; 14 in figure 2) with embedded and exposed portions (depicted in figure 7a and 7b) and conductive core (14a), a primary conductor (14), a porous (see figure 12d – element 96 permits emission of fluid thereby is porous) flexible boot (86,96),

(Office action at page 4).

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Dillon, 919 F.2d 688, 16 USPQ2d 1897. 1908 (Fed. Cir. 1990) (en banc). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236; 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); see also MPEP § 2131.

Regarding claim 65, Applicants respectfully disagree that the claim is anticipated by Goble. Goble does not teach or suggest the invention of claim 65, including the following distinctive features:

a **flexible boot** at said distal end of said outer sheath,

said **flexible boot defining an annular fluid jacket around a booted portion of said flexible electrode**, wherein

said **booted portion comprises at least a portion of said exposed portion of said flexible electrode**, and wherein

said **annular fluid jacket** is adapted to carry fluid that is in fluid communication with said annular channel.

Applicants respectfully assert that Goble's "insulating sleeves" (86 and 96) alleged by the Examiner to constitute a "flexible boot" do not contain all of the elements (or the arrangement of elements) of the "flexible boot" required by Applicants' claims.

First, none of Goble's multiple embodiments teach "insulating sleeves" (86 and 96) that define an "annular fluid jacket" or are "adapted to carry fluid," as required by Applicants' claims. Indeed, the asserted "insulating sleeves" in Goble are structurally different and have a completely different purpose than the "flexible boot" of Applicants' claims. The arthroscopic, vaporizing device of Goble is fundamentally a bipolar electrode operating at very high power levels and temperatures. Not surprisingly, every embodiment of the Goble device describes the use of "insulating sleeves" to electrically separate the "tissue treatment" or "active" electrode from the "return" electrode. Additionally, every embodiment of the bipolar electrode device completes the circuit between the two electrodes through a conductive fluid:

The return electrode is spaced from the tissue treatment electrode so that, in use, it does not contact the tissue to be treated, and so that ***the electrical circuit is always completed by the conductive fluid . . .*** (col. 4, lines 47-50 of Goble).

For example, in Figure 13 of Goble (cited by the Examiner), the conductive fluid flows along the *outside* of the ceramic insulating sleeve (the alleged “flexible boot”) and contacts and exposed “active” electrode (11) in order to complete the circuit to the “return” electrode (12). (See also Figs. 5a-5c of Goble. Elements 34, 36 and 38). The same holds true for Figure 14. Figure 12d of Goble (also cited by the Examiner) shows the distal end of the ceramic insulation sleeve fully open at the distal end. Goble’s mechanism of action requires an unobstructed, uninsulated path between the “active” electrode and the “return” electrode to complete the circuit. Indeed, it would not make sense to constrain the conductive fluid in a manner that would isolate the fluid to a region (or “jacket”) around the active electrode that would prevent completion of the circuit to the return electrode.

In contrast, Applicants’ claim requires that the flexible boot define an *annular fluid jacket* around a *booted portion of the flexible electrode*. At least one embodiment of Applicants’ disclosure recites that the conductive fluid may:

. . . flow through the annular channel between the inner sheath and the outer sheath, past the coils 132 of uninsulated conductive wire, into ***an annular fluid jacket 138 surrounding a region of the brush electrode*** adjacent to the distal ends of the inner and outer sheaths, and then into the sides of the brush electrode itself and through the interstitial gaps between the filaments comprising the brush electrode. ***The ablative energy (e.g., the RF energy 150) is thus carried by the conductive fluid into the core of the brush electrode and toward its working surface 140.*** (Paragraph [0069] of Applicants’ specification as filed; Figure 26).

Applicants’ claim 65 requires an annular ***fluid jacket around a booted portion*** of the flexible electrode. Applicants concede that the insulating sleeves of Goble do appear to be annular. However, they do not constitute a “fluid jacket around a booted portion” of a flexible electrode. Such an element would run counter to the fundamental operation of the bipolar Goble and its absence in Goble is not surprising. For at least this reason, claim 65 is not anticipated by the cited art. Additionally, claims 66-82, which all depend from claim 65, are allowable for at least the same reason.

Secondly, regarding claims 80-82, the anticipation rejection should be withdrawn for an additional and independent reason. Applicants’ claims 80 and 81 recite “hollow

filaments." Claim 82 recites "porous filaments." Applicants' specification makes clear that the hollow or porous filaments refer to the individual filaments as opposed to the electrode itself. "The filament parameters include, for example, the material and structural properties of the *individual filaments* . . ." (Paragraph [0080] of Applicants' specification as filed). Applicants have amended claims 80-82 to more clearly incorporate the "individual filaments" language from the specification into the claims. Because Goble neither teaches nor suggests hollow or porous filaments, the rejections based on anticipation must be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 73-74 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Goble.

The Examiner has alleged that "looped primary conductors as claimed are merely rearrangement of parts found in Goble and are further a mere obvious design choice. . . . "and that the "looped primary conductor as claimed and seen in Applicants' figure 26 would not have modified the operation of the claimed device or that seen in Goble." (Office action at page 4). Applicants respectfully disagree. Applicants also respectfully submit that the choice of a looped primary conductor in some embodiments of Applicants' disclosure is not analogous to the situation cited in *In re Japiske* (the mere movement of a starting switch).

Goble does not teach or suggest a looped primary conductor. In fact, the minimal references to the primary conductor in Goble refer to it as a "central conductor."

The active (brush) electrode 74 is connected to an RF generator (not shown) ***via a central copper conductor (also not shown). A ceramic insulation sleeve 76 surrounds the central conductor***, the filaments 74a of the brush electrode passing along the insulation sleeve and extending laterally therefrom through a cut-out 76a. A return electrode 78, which is constituted by the distal end of the instrument shaft, surrounds the proximal end of the sleeve 76. (Goble, col. 19, lines 37-45; Figure 9)

More importantly, Goble suggests that the choice of a "central conductor" is intentional:

Advantageously, the common electrical supply conductor is a central conductor, the insulation member surrounding the central conductor. (Goble, col. 5, lines 19-21).

The active electrode 11 is held centrally within the return electrode 12 by means of a ceramic insulator/spacer 15. ***The insulator/spacer 15 has a generally cylindrical portion 15a surrounding the junction between the active electrode 11 and the conductor 14*** and the adjacent regions of these two members, and four radially-extending, equispaced wings 15b which contact the internal circumferential wall of the return electrode 12 to hold the insulator/spacer, and hence the active electrode 11, centrally within the return electrode. (Goble, col. 21, lines 8-17; Figure 13)

Once again, the fundamentally different operation of the bipolar electrode in Goble drives the design. The ceramic insulation spacers not only isolate the active electrode from the return electrode, they also isolate the primary conductor. One of skill in the art would immediately appreciate the advantage of a central primary conductor as stated in Goble – it effectively insulates both the active electrode and conductor in an optimum amount of space.

Applicants' disclosure recites several advantages for the "looped" primary conductor, such as:

. . . a loop of wire 114 may be present to help collect and stabilize the filaments 26 during assembly of the catheter 16'. [Paragraph [0068] of Applicants' specification as filed).

. . . [t]hese loops or coils increase the surface area through which the ablative energy is transferred, thereby providing for more effective, and potentially less destructive, energy transfer to the brush electrode 120." (Paragraph [0068] of Applicants' specification as filed).

It is not surprising that Goble does not teach or suggest the use of a looped primary conductor since providing more effective and potentially less destructive energy transfer to the electrode is not one of the design drivers for that device. The Goble reference discloses operation of all of its embodiments at much higher power levels than those found

in Applicants' disclosures. Goble is also replete with references to the primary problem it addresses – the destruction and vaporiz[ation] of arthroscopic tissue. The central location and electrically insulated characteristics of the primary conductor are explicitly stated to be important characteristics in Goble.

In contrast, the looped primary conductor of Applicants' claims confers several structural and electrical advantages as described in the disclosure. Thus, Applicants assert that the choice of a looped primary conductor is not a design choice comparable to the mere placement of the starting switch as found in *In re Japiske*. For at least these additional reasons, claims 73 and 74 are patentable over the Goble reference and the rejections should be withdrawn.

Claims 69-71 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of Wilsdorf.

In order to make out a *prima facie* case of obviousness, "the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). Additionally, "[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done." *In re San Su Lee*, 277 F.3d 1338 (Fed. Cir. 2002). Applicants assert that the evidence of record has not identified an objective source for the motivation to combine Goble with Wilsdorf in the manner proposed.

Applicants submit that the rejections based on the combination of Goble and Wilsdorf should be withdrawn because it is not reasonable to combine Goble with Wilsdorf. Applicants submit Wilsdorf is non-analogous art that one of ordinary skill would not consider relevant to the claimed invention. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." MPEP 2141.01(a). *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ

313 (Fed. Cir. 1986). "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

Wilsdorf does not describe an electrosurgical device or even a medical-based application for a brush electrode. The alleged brush electrode of Wilsdorf is an electrical brush contact typically found in a motor or generator. No one skilled in the art of making catheters would reasonably look to the field of motors and electric generators. They are not reasonably pertinent because they would not logically commend themselves to an inventor's attention in considering this problem – creating medical catheters. The environment in which a medical catheter is typically employed would render a motor or generator inoperable. The problem addressed by Applicants' invention (and the solution it employs) is so far removed from Wilsdorf that no person of ordinary skill in the art would have logically looked in that direction. It would also be unreasonable to expect that one skilled in the art of making medical catheters would possess sufficient knowledge of the field of electric motors and generators to motivate a search of those fields. Wilsdorf is simply directed to non-analogous art. For at least this reason, claim 69-71 and 78 are patentable over Goble and Wilsdorf.

Regarding claim 78, the obviousness rejection should be withdrawn for at least a second and independent reason. The purpose of the non-conductive filaments in Wilsdorf is to provide mechanical support to the conductive filaments of the brush. (Wilsdorf at col. 27:17-18). The non-conductive support fibers can also be distributed in a manner whereby the coefficient of friction and wear is lowered on the conducting fibers (see generally col. 27:18-28:60 of Wilsdorf). In all cases with Wilsdorf, the non-conductive support fibers are either equal in length to the conductive fibers (27:24-27) or shorter than the conductive fibers (28:23-25). In contrast, particular embodiments of Applicants' specification recite making some non-conductive fibers longer than the conductive fibers with the goal of creating a "standoff brush electrode" whereby the "conductive filaments (72) are

interspersed among relatively longer non-conductive filaments (74).” (Applicants’ specification as filed at paragraph [0056], Figs. 8-10). Wilsdorf does not teach or suggest that the conductive fibers can be shorter than the non-conductive fibers. Thus, even if one were to combine Goble and Wilsdorf, the combination still does not yield the claimed invention. For this independent reason, the obviousness rejection of claim 78 should be withdrawn.

For each of the reasons cited above, Applicants respectfully request that the obviousness rejections based on combining Goble with Wilsdorf be withdrawn.

Argument Regarding 102(b) Rejection of Claim 1

The totality of Examiner’s 102(b) rejection has been recited above (page 17).

Applicants respectfully assert that the Examiner has not established a *prima facie* case to support an anticipation rejection of claim 1 and request clarification of the rejection with regard to claim 1. For example, noticeably absent from consideration in the Examiner’s analysis are the following claimed features:

- a.) ***a plurality of flexible filaments adapted to transfer ablative energy to target tissue, said flexible filaments defining interstitial spaces among said plurality of filaments, wherein said interstitial spaces are adapted to carry conductive fluid;***
- b.) ***a primary conductor operatively connected to, and adapted to transfer ablative energy to, said plurality of flexible filaments; and***
- c.) ***a fluid-delivery means adapted to deliver conductive fluid to said interstitial spaces.***

Respectfully, the Examiner has not met his burden of making a *prima facie* case for anticipation with regard to claim 1. Applicants request that the 102 rejection be withdrawn for at least the reason that Goble does not disclose a fluid-delivery means within the

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properly construed meaning of the claims. If the Examiner does not concur, Applicants respectfully request that the Examiner identify with particularity the specific portions of Goble upon which he relies.

Applicants request withdrawal of the Examiner's rejections and submit that the application is in condition for allowance. Timely notification of allowability is requested.

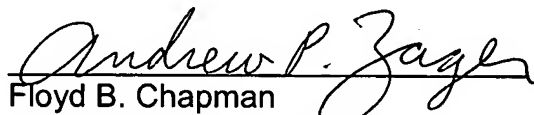
Applicants have requested a one-month extension of time for the filing of this response and submitted the required fee. If any additional fees, petitions, or requests for extension of time are required in order to enter or consider this paper, enter or consider any of the claims submitted, enter or consider any paper accompanying this paper, or keep this application or the previous application pending, Applicants hereby request that the petition or request be granted and Applicants' representative hereby authorizes the Commissioner to charge our Deposit Account No. 50-1129 for any fees.

Respectfully submitted,

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